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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,749	08/13/2002	Robert David Darrow	RD27658	8455
6147	7590	02/24/2005	EXAMINER	
GENERAL ELECTRIC COMPANY GLOBAL RESEARCH PATENT DOCKET RM. BLDG. K1-4A59 NISKAYUNA, NY 12309			SULLIVAN, JULIANNE M	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/064,749

Applicant(s)

DARROW ET AL.

Examiner

Julianne M. Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The following typographical error was noted in the specification: in paragraph 30, line 8, "biopsyIn." Appropriate correction is suggested.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 1, 7-9, 13-15, 23 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 3, 14, 16 and 17 of U.S. Patent No. 5,211,165 to Dumoulin et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same tracking and positioning system for medical devices used within the body.

Regarding Claims 1, 7, 13 and 23 of the present application, Dumoulin et al. '165 claims a medical device adapted for internal use (Claim 1, col. 7, line 50), an imaging device (Claim 1, col. 7, lines 63-65), and a medical device monitoring subsystem that monitors the position of the device and provides feedback when the device leaves the region of interest (Claim 1, col. 7, lines 59-62 and 66-68 and col. 8, lines 1-5). Dumoulin et al. '165 further claims a tracking device for tracking the location of the medical device (Claim 1, col. 7, lines 51-62) and a processor coupled to the medical imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images and the processor is further adapted to monitor a position of the medical device relative to the region of interest (Claim 1, col. 7, lines 66-68 and col. 8, lines 1-5).

Regarding Claims 8, 14 and 27 of the present application, Dumoulin et al. '165 claims an imaging system that may be an X-ray imaging system (Claim 14, col. 9, lines 35-37), an MRI system (Claim 16, col. 10, lines 1-3) or a PET system (Claim 17, col. 10, lines 4-6).

Regarding Claims 9 and 15 of the present invention, Dumoulin et al. '165 claims an invasive device that may be a guide wire, a catheter, an endoscope, a laparoscope or a biopsy needle (Claim 3, col. 8, lines 32-35).

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4. Claims 2-6, 10, 16-19, 22, 24-26 and 28-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 5,211,165 in view of Dumoulin et al. (U.S. Patent No. 5,251,635).

Regarding Claims 2-4, 22 and 25, Dumoulin et al. '165 claims all of the features of the present invention, as discussed above, except for expressly stating that the monitoring subsystem receives configuration information corresponding to the medical device comprising at least one of three-dimensional coordinates of the device, tracking method information, physical dimensions of the device and a model representation of the device, that the monitoring subsystem is responsive to movement of the subject or of the medical device relative to the target region and that the subsystem has a predetermined response of at least one of terminating the therapy, activating the imaging system to acquire a new image and activating an advisory message.

In the same field of endeavor, Dumoulin et al. '635 teaches all of the above limitations. The '635 patent teaches that the monitoring subsystem receives configuration information corresponding to the medical device that is tracking method information (col. 4, line 68 and col. 5, line 1), that the monitoring subsystem is responsive to movement of the medical device relative to the target region (col. 7, lines 24-37) and that the subsystem has a predetermined response of activating the imaging system to acquire a new image (col. 7, lines 31-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the features of the monitoring subsystem of Dumoulin et al. '635 with the monitoring subsystem of Dumoulin et al. '165 in order to allow the operator to choose the tracking method used and to

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provide new images when the device has moved without requiring additional operator action (see for motivation Dumoulin et al. '165 at col. 7, lines 29-32).

Regarding Claims 5, 6, 17, 19 and 24, Dumoulin et al. '165 claims all of the features of the present invention, as discussed above, except for expressly stating that the subsystem provides advisory feedback to the interface unit and that the advisory feedback is at least one of a visual icon representing the position of the device, a text message and an advisory.

In the same field of endeavor, Dumoulin et al. '635 teaches that the subsystem provides advisory feedback to the interface unit (col. 3, lines 1-4, col. 4, lines 42-46 and col. 7, lines 31-39) and that the advisory feedback is a visual icon representing the position of the device (col. 3, lines 22-25 and col. 4, lines 19-21 and 25-35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the feedback of Dumoulin et al. '635 in the system of the '165 patent in order to allow the operator to track the location of the device.

Regarding Claims 10, 16, 18, 26 and 28-30, Dumoulin et al. '165 claims all of the features of the present invention, as discussed above, except that the interface responds to operator input of coordinates of the desired target position of the medical device, that there is a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device, and that the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest.

In the same field of endeavor, Dumoulin et al. '635 teaches that the interface responds to operator input of coordinates of the desired target position of the medical device (col. 7, lines 38-

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43), a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device (col. 3, lines 1-4), where the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest (col. 2, lines 25-28 and col. 7, lines 31-39 and 61-65).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine these features of the '635 patent with those of the '165 patent in order to provide imaging or therapy at the appropriate location and in order to provide improved placement of the device.

5. Claims 2, 11, 12, 20 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 5,211,165 in view of Panescu et al. (U.S. Patent No. 5,916,163).

Dumoulin et al. '165 claims all of the features of the present invention, as discussed above, except for expressly stating that the monitoring subsystem receives configuration information about the device that is a model representation, where that information corresponds to a visual representation of the device for superimposing on the images acquired, and where the visual representation is a wire-frame model of the device.

In the same field of endeavor, Panescu et al. teaches a system for locating and positioning a catheter within a body where configuration information about the device is entered into the processing system (col. 6, lines 56-59). Panescu et al. also teaches that a graphical representation of the device may be provided and that the representation may be used in combination with the fluoroscopic images of the position of the device (col. 6, lines 31-46).

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Further, Panescu et al. teaches that a wire-frame image of the device may be used (col. 6, lines 47-48).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the configuration input scheme and visual representations of Panescu et al. with the system of Dumoulin et al. '165 in order to provide the operator with improved orientation of the device within the subject (see for motivation Panescu et al. at col. 5, lines 65-67 and col. 6, lines 6-12).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-9, 13-15, 17, 19, 22-25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumoulin et al. (U.S. Patent No. 5,211,165).

Regarding Claims 1, 7, 13 and 23, Dumoulin et al. '165 teaches a medical device positioning system and a method for positioning a device comprising an internal medical device, an imaging device, a medical device monitoring subsystem that monitors the position of the device and provides feedback to an interface, a tracking device, and a processor coupled to the medical imaging device and tracking device for generating images (col. 2, lines 46-51, 53-57 and 61-65, col. 3, lines 23-27, col. 4, lines 4-7 and col. 7, lines 18-32).

Regarding Claim 2, Dumoulin et al. '165 teaches a monitoring subsystem adapted to receive configuration information that is tracking method information corresponding to the medical device (col. 4, lines 58-60).

Regarding Claims 3, 4, 22 and 25, Dumoulin et al. '165 teaches a monitoring subsystem responsive to the movement of the medical device relative to the target region within the subject (col. 7, lines 18-32) and a monitoring subsystem that responds to movement of the medical device by activating the imaging system to acquire a new image (col. 7, lines 26-32).

Regarding Claims 5, 6, 17, 19 and 24, Dumoulin et al. '165 teaches a monitoring subsystem that provides advisory feedback where the feedback is a visual icon representing the location of the device (col. 2, lines 54-57, col. 3, lines 9-12, col. 4, lines 8-10, 14-24 and 31-36 and col. 7, lines 26-32).

Regarding Claims 8, 9, 14, 15 and 27, Dumoulin et al. '165 teaches that the imaging device may be an MRI scanner, an X-ray device, a PET system or an ultrasound scanner and that the invasive device may be a guide wire, laparoscope, catheter, biopsy needle or other invasive devices (col. 1, lines 25-26 and 50, col. 7, lines 33-38).

8. Claims 1-10, 13-19 and 22-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumoulin et al. (U.S. Patent No. 5,251,635).

Regarding Claims 1, 7, 13 and 23, Dumoulin et al. '635 teaches a medical device positioning system and a method for positioning a device during a medical procedure on a subject performed during imaging comprising:

a medical device adapted for internal use within the subject for performing the medical procedure (col. 1, lines 60-63, col. 2, line 68 and col. 3, line 1);

an imaging device for acquiring image data of a region of interest within the subject (col. 2, lines 2-10 and 61-66);

a medical device monitoring subsystem for monitoring the position of the medical device relative to a target region of interest within the subject and for providing feedback to an interface unit when the position of the medical device deviates from the target region of interest (col. 3, lines 1-4 and 35-39 and col. 7, lines 24-37);

a tracking device for tracking a location of the medical device (col. 3, lines 12-16); and,
a processor coupled to the medical imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images and the processor is further adapted to monitor a position of the medical device relative to the region of interest, the processor responding to change in the position and providing feedback to an interface (col. 3, lines 35-39, col. 4, lines 16-19 and col. 7, lines 24-37).

Regarding Claim 2, Dumoulin et al. '635 teaches a monitoring subsystem adapted to receive configuration information that is tracking method information corresponding to the medical device (col. 4, line 68 and col. 5, line 1).

Regarding Claim 3, Dumoulin et al. '635 teaches a monitoring subsystem responsive to the movement of the medical device relative to the target region within the subject (col. 7, lines 24-37).

Regarding Claims 4, 22 and 25, Dumoulin et al. '635 teaches a monitoring subsystem that responds to movement of the medical device by activating the imaging system to acquire a new image (col. 7, lines 31-37).

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Regarding Claims 5 and 19, Dumoulin et al. '635 teaches a monitoring subsystem that provides advisory feedback to the interface unit when the medical device deviates from a target position (col. 3, lines 1-4, col. 4, lines 42-46 and col. 7, lines 31-39).

Regarding Claims 6, 17 and 24, Dumoulin et al. '635 teaches a monitoring subsystem where the advisory feedback is a visual icon representing the position of the device (col. 3, lines 22-25 and col. 4, lines 19-21 and 25-35).

Regarding Claims 8, 14 and 27, Dumoulin et al. '635 teaches an imaging device that may be an MRI scanner, an X-ray device, a PET system, an ultrasound scanner or any other similar medical diagnostic imaging device (col. 7, lines 66-68 and col. 8, lines 1-3).

Regarding Claims 9 and 15, Dumoulin et al. '635 teaches an invasive device that may be at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser (col. 1, lines 60-63).

Regarding Claims 10, 18 and 26, Dumoulin et al. '635 teaches an interface where the operator selects the desired position of the device (col. 7, lines 38-43).

Regarding Claims 16 and 28-30, Dumoulin et al. '635 teaches a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device (col. 3, lines 1-4), where the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest (col. 2, lines 25-28 and col. 7, lines 31-39 and 61-65).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2, 11, 12, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '635 in view of Panescu et al. (U.S. Patent No. 5,916,163).

Dumoulin et al. '635 teaches all of the features of the present invention except that the monitoring subsystem receives configuration information about the device that is a model representation, where that information corresponds to a visual representation of the device for superimposing on the images acquired, and where the visual representation is a wire-frame model of the device.

In the same field of endeavor, Panescu et al. teaches a system for locating and positioning a catheter within a body where configuration information about the device is entered into the processing system (col. 6, lines 56-59). Panescu et al. also teaches that a graphical representation of the device may be provided and that the representation may be used in combination with the fluoroscopic images of the position of the device (col. 6, lines 31-46). Further, Panescu et al. teaches that a wire-frame image of the device may be used (col. 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the configuration input scheme and visual representations of Panescu et al. with the system of Dumoulin et al. '635 in order to provide the operator with improved

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orientation of the device within the subject (see for motivation Panescu et al. at col. 5, lines 65-67 and col. 6, lines 6-12).

11. Claims 6, 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '635 in view of Twiss et al. (U.S. Patent No. 5,375,596).

Dumoulin et al. '635 teaches all of the features of the present invention except for expressly providing that the advisory feedback may be an audible advisory. In the same field of endeavor, Twiss et al. teaches a method and apparatus for locating catheters or other devices within biological tissue where an audible tone is used to indicate proximity to the desired location (col. 7, lines 1-4 and 23-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the audible advisory of Twiss et al. in the system of Dumoulin et al. '635 so that the operator receives location information without the necessity of his looking away from the patient to a display screen.

12. Claims 10, 16, 18, 26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '165 in view of Dumoulin et al. '635.

Regarding Claims 10, 18 and 26, Dumoulin et al. '165 teaches all of the features of the present invention except for expressly stating that the interface responds to operator input of the desired position of the device. In the same field of endeavor, Dumoulin et al. '635 teaches an interface where the operator selects the position of the device (col. 7, lines 38-43). It would have been obvious to one of ordinary skill in the art at the time of the invention to have added this feature of the '635 patent to the system of the '165 patent in order to provide imaging or therapy at the appropriate location.

Regarding Claims 16 and 28-30, Dumoulin et al. '165 teaches all of the features of the present invention except for expressly stating that there is a coupling between the interface and the processor that allows display of images and response to movement in real time and that the feedback may be used to navigate the device. In the same field of endeavor, Dumoulin et al. '635 teaches a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device (col. 3, lines 1-4), where the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest (col. 2, lines 25-28 and col. 7, lines 31-39 and 61-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the real-time response of Dumoulin et al. '635 in the system of Dumoulin et al. '165 in order to provide improved placement of the device. When inserting an invasive device into the body, both the ultimate location as well as the path the device takes to reach that location are critical in order to avoid unnecessary damage to tissues, therefore it would be obvious to use a system that provides a more accurate and contemporaneous location for the device.

13. Claims 2, 11, 12, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '165 in view of Panescu et al.

Dumoulin et al. '165 teaches all of the features of the present invention except that the monitoring subsystem receives configuration information about the device that is a model representation, where that information corresponds to a visual representation of the device for

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superimposing on the images acquired, and where the visual representation is a wire-frame model of the device.

In the same field of endeavor, Panescu et al. teaches a system for locating and positioning a catheter within a body where configuration information about the device is entered into the processing system (col. 6, lines 56-59). Panescu et al. also teaches that a graphical representation of the device may be provided and that the representation may be used in combination with the fluoroscopic images of the position of the device (col. 6, lines 31-46). Further, Panescu et al. teaches that a wire-frame image of the device may be used (col. 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the configuration input scheme and visual representations of Panescu et al. with the system of Dumoulin et al. '165 in order to provide the operator with improved orientation of the device within the subject (see for motivation Panescu et al. at col. 5, lines 65-67 and col. 6, lines 6-12).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chader et al. (U.S. Patent No. 5,617,857) discloses a related tracking and imaging system for invasive devices.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianne M. Sullivan whose telephone number is 571-272-6084. The examiner can normally be reached on Monday through Friday 8:00am to 4:30pm.

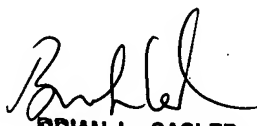
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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